UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al. ex rel.* ADAM HART, Plaintiff(s), v. MCKESSON CORPORATION, *et al.,* Defendant.	No.: 15-Civ-0903 (RA) (JC) **MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS**

COVINGTON & BURLING LLP

Ethan M. Posner*
Shanya Dingle
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW Washington, DC 20001
Tel: 202.662.6000
eposner@cov.com
sdingle@cov.com
**Pro hac vice application to be filed*

Elisa S. Solomon
The New York Times Building
620 Eighth Avenue
New York, New York 10018
esolomon@cov.com

Attorneys for Defendants

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases ..... **Page(s)**

Statutes

Other Authorities

INTRODUCTION

In this government-declined *qui tam* case, Plaintiff-Relator Adam Hart ("Hart") asserts that Defendants McKesson Corporation, McKesson Specialty Distribution LLC, McKesson Specialty Care Distribution Corporation (collectively "Defendants" or "McKesson") violated the Anti-Kickback Statute ("AKS") and False Claims Act ("FCA") by making available to its customers simple spreadsheet and web-based calculation tools containing a customer's own purchasing information as well as public reimbursement information. The Relator hypes these freely and widely available items as "valuable business-management tools designed to quantify" the financial implication of medication decisions as "as an inducement to purchase drugs from McKesson." *See* Am. Compl. ¶ 3, ECF No. 16 [hereinafter "AC"].

But calling publicly available business management tools "kickbacks" does not make it so. The "management tools" that are the focus of the AC — Margin Analyzer ("MA") and Regimen Profiler ("RP") — merely provide customers with their own drug purchase history and pricing information, as well as public reimbursement information for those drugs. Exhibit 1 to the AC, in fact, merely compares pricing data in an Excel spreadsheet. Similar spreadsheets and calculators that permit pricing and margin comparisons between therapeutically equivalent medicines and treatment regimens are widely and *publicly* available, including by institutions like Sloan Kettering and by other distributors. They are not "kickbacks" in violation of the FCA.

The United States investigated these claims and declined to intervene, and 29 States have also declined to pursue this case. Now the Court should dismiss this case under Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure, for at least three reasons.[1]

[1] Relator's allegations also raise significant commercial speech defenses under the First Amendment. The provision of pricing and reimbursement data to physician practices is clearly protected commercial speech. *See, e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer*

First, the Court should dismiss this case because the MA and RP analytic tools provide no substantial or independent value and are not prohibited remuneration. The relevant guidance issued by the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"), and cases applying them, instruct that basic analytical tools such as those alleged in the AC are not only common, but appropriate and beneficial so long as they do not provide *substantial and independent* value to the prescriber. Relying on this OIG guidance, at least two courts have dismissed analogous FCA/AKS claims under Rules 9 and 12 because the *qui tam* relators pursuing those actions failed to allege that the challenged basic analytical tools had substantial and independent value. *See U.S. ex rel. Suarez v. AbbVie, Inc.*, No. 15-C-8928, 2019 WL 4749967 (N.D. Ill. Sept. 30, 2019); *U.S. ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568 (E.D. Pa. June 19, 2017) ("*Forney*").

The Court should dismiss the AC for similar reasons, as Hart's allegations, even taken as true, do not establish a violation of the AKS because they do not demonstrate that providing MA or RP offers either 1) substantial or 2) independent value. The tools described in Hart's allegations do not provide *substantial* value because they offer information that is *available at no cost over the Internet*. Similar and at times nearly identical analytic tools are easily found and used on web sites, and promulgated by medical institutions, medical societies, and other drug distributors. Even McKesson's own MA and RP tools, about which Relator complains are secret

---

Council, Inc., 425 U.S. 748 (1976) (recognizing that the provision of drug pricing information is protected speech); *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 577–78 (2011) ("[T]he 'fear that people would make bad decisions if given truthful information' cannot justify content-based burdens on speech." (citation omitted)); *id* at 577–78 ("[T]he State defends the law by insisting that 'pharmaceutical marketing has a strong influence on doctors' prescribing practices.' []. This reasoning is incompatible with the First Amendment." (citation omitted)); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) (recognizing that commercial medical promotion is protected speech).

kickbacks, are easily discovered in the public domain.[2] Additionally, the business analytical tools do not provide *independent* value to the prescriber, because these tools are obviously linked to the sale of McKesson products and did not allow healthcare providers to avoid or reduce expenses they would otherwise incur in the ordinary course.

Second, the AC should be dismissed because it does not even allege the required intent element under the AKA. The law requires that Relator prove knowing and willful intent, which here requires that the company knew its MA and RP were wrongful kickbacks. There is no — and cannot be — such an allegation in the AC. To the contrary, the AC alleges wide dissemination and discussion within the company about the MA and RP tools, *see, e.g.*, AC ¶¶ 108–09, and nothing to indicate the company or its personnel were acted secretly or were concerned such tools were wrongful. Nor can Relator explain how it could allege such knowing and willful intent when the MA and RP tools were in the public domain and freely and publicly available from other distributors.

Finally, the AC fails to plead with any particularity that false claims were submitted to the government. The AC alleges that several physician practices received MA or RP, AC ¶ 53, but there is no particular allegation of how or whether these practices used these tools, how or whether these practices made treatment or prescribing decisions using these tools, whether to benefit McKesson or not. Nor is there any allegation of any specific claim for reimbursement to the government resulting from a practice receiving those tools. There is only the allegation that "many" practices used MA or RP to "purchase the highest-margin drugs among therapeutically interchangeable alternatives," AC ¶ 116, but no allegation of a specific claim for reimbursement

[2] *See, e.g.*, Ex. A, McKesson, *Regimen Profiler: Valuable Insight for You and Your Patients*, https://medifacd.mckesson.com/uploadedFiles/McKessoncom/Content/About_Us/Our_Company/Our_Businesses/Specialty_Health/Regimen_Profiler_Sell_Sheet_Rheumatology.pdf (2011),

that resulted from such an indeterminate medical prescription. Nor is there any allegation of any prescription that imposed higher costs on the government, and indeed the AC itself contains examples where lower cost generic medicines may have been selected. AC ¶¶ 73–74.

The AC concedes that Relator "does not possess comprehensive records" pertaining to the prescribing decisions of the McKesson customers, AC ¶ 122, but that is an understatement. The Relator alleges only that customers in several states received the MA and RP tools, but he cannot identify a single specific customer that purchased McKesson products or any specific prescribing determination that was made because of these tools, or a *single reimbursement claim* that resulted from using these tools. All that is alleged is that "[o]n information and belief," various unnamed customers submitted unidentified claims in various states. AC ¶ 122. That is plainly insufficient under Rules 12 and 9(b). The AC should now be dismissed.

STATEMENT OF THE CASE

Hart initiated this action on February 6, 2015, by filing under seal this *qui tam* action asserting claims on behalf of the United States and 29 States and the District of Columbia under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and state false claims statutes. Over a period of several years, the United States investigated these claims and declined to intervene, and 29 States have also declined to pursue this case through their state false claims statutes. The Court ordered the complaint unsealed on May 29, 2020 (ECF No. 15) and Relator filed the AC on June 3, 2020, which was unsealed on July 10 (ECF No. 24).

A. The AC Fails To Allege That MA And RP Offer Substantial Or Independent Value.

The AC alleges that the MA is a spreadsheet that "identifies all pharmaceutical drugs a practice purchases [from McKesson] and all available 'therapeutically interchangeable' alternatives to those drugs." AC ¶ 4. The spreadsheet, attached as Exhibit 1 to the AC, includes a "Therapeutic Interchange Calculator" that calculates the difference between the price for which

McKesson sells a drug and the reimbursement for that drug "by a government health care program or private insurer" and then "estimates (from prior usage) the potential increase in profit a practice could realize if it prescribed only the highest-margin drugs McKesson sells." AC ¶ 4. The RP is "web-based" and "compares a practice's reimbursement for a treatment regimen to the practice's cost of providing that regimen (including the cost associated with purchasing (from McKesson) and selling each interchangeable drug), and calculates the potential increase in profit a practice could realize by using only the most profitable alternative regimen." AC ¶¶ 5, 96. The AC describes that the RP "generates customized financial-responsibility reports that enable physicians to talk to patients about their out-of-pocket costs of care." AC ¶ 96; *see also* AC ¶ 99. The AC provides a conclusory allegation that the MA and RP tools have "significant independent value," AC ¶ 3, but the AC fails to acknowledge that these basic analytical tools provide information that is widely and publicly available. And the AC itself includes exhibits showing that MA and RP were available to all customers.[3]

B. The AC Fails To Allege How MA And RP Caused Any Improper Prescription Determination, Much Less Any Specific False Claim Submitted To The Government.

The AC alleges that "[g]iving away valuable business-management tools at no cost induced scores of physician practices to buy drugs from McKesson rather than its competitors." AC ¶ 116. There is also the conclusory allegation that "claims" were submitted to federal and state government reimbursement programs. AC ¶¶ 121–22. But other than identifying a few customers that received access to MA and RP, AC ¶ 53, the AC fails to allege *a single instance*

[3] *See* Ex. 3 to AC, at 20 (referencing question of "[w]ho makes a good target for Margin Analyzer?" with the answer "[a]ny McKesson Specialty Health practice would benefit from this tool"); *id.* at 21 (referencing question of who has access to MA with the answer that it is "available to all McKesson Specialty Health practices, with no prerequisites" other than information in McKesson's sales database).

of a physician office making a prescription determination based on the MA or RP; or whether that determination resulted in higher reimbursements, as often the MA identified lower cost generic alternatives.[4] Nor does the AC identify a single false claim even though the Relator alleges he has inside information and worked with his accounts for years. At bottom, the AC alleges that customers received the MA and RP tools and eventually false claims must have resulted somewhere, based on some hypothetical prescription by some unnamed physician somehow caused by using the MA or RP tools.

LEGAL STANDARD

To survive a motion to dismiss for failure to state a claim upon which relief may be granted under Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation omitted). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." *Lorenzana v. S. Am. Rests. Corp.*, 799 F.3d 31, 34 (1st Cir. 2015) (internal quotation omitted).

Claims brought under the FCA are also subject to the heightened pleading standard of Rule 9(b), which means that FCA complaints must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). To satisfy this heightened pleading requirement, "an ample factual basis must be supplied to support the charges." *Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 747 (2d Cir. 2009). In addition, "'allegations of

[4] The AC itself cites an example where it was more advantageous to the physician office to prescribe a lower cost generic medicine. *See* AC ¶ 73–74, 82 (MA identified the generic medicine Granisetron as providing a higher margin for the practice but at a lower cost to the government).

violations of federal regulations are insufficient to establish a claim under the FCA if plaintiff cannot identify, with any particularity, the actual false claims submitted by the defendant.'" *Ping Chen ex rel. U.S. v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282, 301 (S.D.N.Y. 2013) (Abrams, J.); *see also id.* at 302 ("Nowhere in the Complaint, however, does Plaintiff identify a particular false claim that was submitted to the government for payment by any Defendant. Dismissal is appropriate on this basis."). In particular, where a complaint is submitted "on information and belief" and not based on allegations of particular claims, the complaint is require[d] to "'adduce specific facts supporting a strong inference of fraud.'" *U.S. ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 82 (2d Cir. 2017) (citing *Wexner v. First Manhattan Co.*, 902 F.2d 169, 172 (2d Cir. 1990)).

ARGUMENT

I. The AC Must Be Dismissed Because It Does Not Sufficiently Allege That MA And RP Constitute Illegal Remuneration Under The AKS.

The Court should dismiss the AC because it fails to allege with particularity the basic AKS element of "remuneration." 42 U.S.C. § 1320a-7b(b)(2). The HHS OIG has issued guidance on the AKS implications of basic analytical tools provided to potential purchasers of reimbursable medicines. These guidance documents confirm that basic analytical tools such as those alleged in the AC are not only common, but appropriate and beneficial so long as they do not provide substantial and independent value to the prescriber. Under the relevant OIG guidance, to allege even the basics of an AKS violation, Hart has to plead at a minimum that a tool has (1) *substantial* and (2) *independent* value. Hart, who bears the burden of alleging each element, cannot show that MA and RP either 1) provided physician practices with substantial benefits or 2) conferred independent value to healthcare providers.

A. Relevant OIG Guidance Advises That Tools Like MA And RP Cannot Be Kickbacks If They Did Not Confer Substantial And Independent Value To Prescribers.

First, under the relevant OIG guidance, items or services provided to healthcare providers that have nominal value lack, by definition, substantial and independent value. An obvious example of this are services that are offered by others for free or for a nominal amount, or available publicly, including over the Internet. Specifically, the OIG has advised that something may have nominal remunerative value under the AKS when "[s]imilar information content is available on the Internet and from other public sources without charge." OIG Adv. Op. No. 07-16, 2007 WL 6400843, at *3 (Dec. 5, 2007). For example, one OIG opinion determined that patient education videos had nominal remunerative value under the AKS because similar content was publicly available at no cost on the Internet and from other public sources without charge. *Id.* Services with nominal value do not qualify as remuneration under the AKS. *See* OIG Compliance Program Guidance for Pharm. Mfrs., 68 Fed. Reg. 23,731, 23,735 (May 5, 2003) ("2003 OIG Guidance") ("Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute.").[5]

Second, the OIG has also instructed that an item or service is not a kickback if it does not provide a healthcare provider *independent* value apart from the products purchased. In other words, "services [that have] no independent value to providers apart from the products . . . are properly considered part of the products purchased" and do not implicate the AKS. OIG Adv.

[5] Courts regularly consider OIG guidance in cases involving the AKS. As one court described, "Because of the continually evolving nature of the health care industry, the OIG 'facilitate[s] the enforcement of" the AKS and other statutes, 42 U.S.C. § 1320a-7c, by issuing advisory opinions as to "[w]hat constitutes prohibited remuneration" and "[w]hether an arrangement . . . satisfies the criteria" for certain safe harbors. 42 C.F.R. 1008.5(a)(1) – (2)." *Health Choice All., LLC, on behalf of United States v. Eli Lilly & Co., Inc.*, No. 5:17-CV-123-RWS-CMC, 2018 WL 4026986, at *17 (E.D. Tex. July 25, 2018), report and recommendation adopted, No. 5:17-CV-123-RWS-CMC, 2018 WL 3802072 (E.D. Tex. Aug. 10, 2018).

Op. No. 00-10, 2000 WL 35747420, at *4 (Dec. 15, 2000). In determining whether a support service has independent value, numerous OIG opinions have explained that business tools have no independent value where "the item or service offered can be used only as part of the underlying service being provided." OIG Adv. Op. No. 12-19, 2012 WL 7148095, at *8 (Nov. 30, 2012). For this reason, the OIG has opined frequently that billing and reimbursement assistance services, even those extensively staffed and maintained by a manufacturer or distributor, have no substantial independent value to the purchaser where they are tailored to the company's products.[6]

The OIG has applied this legal framework to technology tools furnished to healthcare professionals. So long as the tool is incident to the sale of the product and of no independent value outside the parties' commercial relationship, it does not constitute remuneration under the AKS. Accordingly, a computer, the OIG noted long ago, "would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory company."[7] The OIG elaborated that "free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services from the donor would be integrally related to the donor's services" such that the computer "would have no independent value to the recipient apart from the services the donor provides and, therefore, would not implicate the anti-kickback statute." *Id.*

---

[6] Medicare and State Health Care Programs: Fraud and Abuse; Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013) ("Electronic Health Records Safe Harbor Under the Anti-Kickback Statute"); OIG Adv. Op. 16-09, 2016 WL 5852763 (Sept. 16, 2016) (applying this logic); OIG Adv. Op. 12-19 (same); OIG Adv. Op. 10-20, 2010 WL 3897164 (Sept. 21, 2010) (same); OIG Adv. Op. 08-06, 2008 WL 6067516 (May 2, 2008) (same).

[7] Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. at 79,210 (citing OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,978 (July 29, 1991) (preamble to the 1991 electronic health records safe harbor regulations)).

More recently, the OIG has approved a variety of electronic interfaces and other software products — tools far more complex than the simple analytic and comparative formulas produced by MA and RP — noting that "[i]t is the lack of independent value to the recipient that takes [a] donation outside the scope of the anti-kickback statute's prohibition, not the mode of technology." *Id.*; *see also, e.g.*, OIG Adv. Op. 12-20, 2012 WL 7148096 (Dec. 12, 2012). For example, the OIG considered a program offered by a pharmaceutical manufacturer designed to promote a specific drug that was comprised of "several components, including prequalification of patients for third party coverage and reimbursement, extended payment terms for participating physicians, and credits for denied claims." OIG Ad. Op. 00-10, at *2. The OIG found the program did not constitute prohibited reimbursement because it was clearly linked to medicines made by the manufacturer. Likewise, the OIG found that a hospital's provision of an electronic interface through which physicians could transmit orders for and receive results from laboratory and diagnostic services did not constitute prohibited remuneration. OIG Adv. Op. No. 12-20 at *1, 3. The OIG reasoned that access "would be integrally related to the [hospital's laboratory and diagnostic] services, such that free access would have no independent value to [participating physicians] apart from the services the [hospital] provides." *Id*. at *3.

B. Cases Applying The OIG Guidance Have Dismissed Analogous Cases Involving Tools And Services That Do Not Confer Substantial And Independent Value To Providers.

Courts have relied upon this OIG guidance in dismissing analogous cases involving business support services that do not confer substantial and independent value to health care providers.

In *Forney,* the relator claimed that Medtronic had provided illegal kickbacks to cardiologists who purchased products that must be implanted into patients, such as defibrillators and heart monitoring devices. 2017 WL 2653568 at *1. Per the relator's allegations, "[w]hile

the medical devices at hand were 'off-the-shelf commodities,' were not new to cardiologists, and had been approved by the United States Food and Drug Administration for at least five years," Medtronic provided its customers "free surgical support, implant device follow-up that it continued to offer long after device implantation, and free staff to clinics at which Medtronic employees would spend four to eight hours conducting interrogations and other services" in order to induce physicians to purchase their products. *Id.* Even though these "business support" services were characterized by the relator in that matter as "free labor [that] benefitted [the physicians'] bottom line," *id.* (second alteration in original), the district court dismissed the case. The court determined that relator had failed to demonstrate "any independent value to the purchaser was *substantial*," as "[s]imply stating that the services generally benefited Medtronic's customers' bottom lines or that physicians used Medtronic's services 'in lieu of having to pay for their own employees,' is not sufficiently specific . . . without alleging *how* those services substantially benefited customers' bottom lines." *Id.* at *4, *relying on* 2003 OIG Guidance, 68 Fed. Reg. at 23,735. The court also concluded that the relator failed to "describe with sufficient specificity how Medtronic's free services crossed the line separating permissible product support from illegal remuneration with *independent* value to the purchaser" without specifying which services "that Medtronic provided in exchange for purchasing Medtronic products would have had to have been otherwise performed by the physician or the physician's staff." *Id.*[8]

Similarly, in *Suarez* , the relator alleged an AKS violation based on basic management tools provided by AbbVie for Humira, an injectable drug that treats various autoimmune

[8] After dismissal, Forney filed a new complaint with significant new detail that Medtronic employees assisted with clerical tasks, such as data entry and scheduling, *Forney*, Second Am. Compl. ¶¶ 32, 33, 36, 40, and performed hospital functions that would otherwise be provided by a clinical technician, id. ¶¶ 26, 36. There is no such detail here. And even with this detail, the court was still "reluctant" to let the case proceed.

diseases, 2019 WL 4749967 at *1, in the form of providing patients "training on obtaining insurance payments for Humira, self-injecting the drug, and discarding injection equipment" and fielding "administrative questions from patients concerning Humira" that are received by doctor's offices. *Id.* at *3. Once again, even though the relator alleged that AbbVie representatives "'off- load[ed] the work of [doctors'] office[s], thus providing free and valuable services,' . . . 'the collective value' [of which] 'is enormous,'" *id.* at *3 (second and third alterations in original), the district court dismissed the case, relying on OIG guidance. *See id.* at *7 ("[T]he court will hew closely to the [OIG] guidance in determining whether Relator has alleged illegal remunerations with particularity.").

First, the court found that the relator "has not sufficiently explained how the services provided *substantial* independent value . . . for physicians," despite having "offered details concerning the type of services [AbbVie] provided." *Id.* at *8 (emphasis added). The relator's allegations that physicians allegedly saved money due to AbbVie's services were insufficient because, "[t]hough he names doctors that benefitted from [AbbVie's] Program generally, Relator does not allege that any doctors (let alone any specific doctors) reduced their expenses or downsized their own staff as a result of [AbbVie's] support services." *Id.* at *9; *see also Health Choice Grp., LLC v. Bayer Corp.*, No. 5:17-CV-126-RWS-CMC, 2018 WL 3637381, at *40 (E.D. Tex. June 29, 2018) (allegations concerning free, product-specific nurse and reimbursement support services failed because relators did not allege that services allowed any single doctor to eliminate administrative staff positions or "increase patient visits," nor did relators identify any single doctor who "actually received 'substantial value'"), *report and recommendation adopted*, 2018 WL 3630042 (E.D. Tex. July 31, 2018). The court also determined that relator had not sufficiently alleged *independent* value by alleging that AbbVie

"provided non-Humira-related goods or services 'in tandem with' Humira-related services." *Suarez*, 2019 WL 4749967, at *7 (quoting 2003 OIG Guidance, 68 Fed. Reg. at 23,735).

Second, the court also concluded that relator failed to plead sufficiently that "Humira-related 'goods or services provided by [AbbVie] eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician).'" *Id.* at *8 (quoting 2003 OIG Guidance, 68 Fed. Reg. at 23,737). In so finding, the court rejected relator's "conclusory allegation that physicians and their staff must 'otherwise . . . perform[]' the services" provided by AbbVie, *id.* (alteration in original), determining instead that the services described in the complaint were the "exact type" of permissible "'support services' a pharmaceutical manufacturer offers 'in connection with the sale of its own products'[,] including 'billing assistance tailored to the purchased products' and 'reimbursement consultation,'" *id.* (quoting 2003 OIG Guidance, 68 Fed. Reg. at 23,735).

C. Like The Services Approved In Relevant OIG Guidance, The MA And RP Tools Do Not Offer Substantial Value Because Tools With Similar Functionality Are Publicly Available.

At the outset, the AC contains the same type of conclusory allegations concerning the value of the MA and RP tools as were found deficient in *Forney* and *Suarez*. The AC alleges only that the tools were provided "at no cost," made the practices more profitable, and had "value for which practices would otherwise pay substantial sums of money." AC ¶ 50. But there is no example at all of a practice paying for these tools, or hiring some outside consultant to furnish these analytic calculators, even though the relator alleges he interacted with numerous physician practices for years.[9] There is not even a specific example of a physician practice

[9] The AC alleges that "[w]hen physician practice groups that were moving or considering moving their business to McKesson's competitors sought to purchase or otherwise maintain

actually using the calculator tools to increase profitability. Distributors and pharmaceutical manufacturers often provide no cost business tools that in theory could make a physician office more profitable, but that does not make them kickbacks; it is the value of the (in this case publicly available) calculators that are relevant, not some theoretical increase in profitability that can be gained using the simple calculator. Both *Forney* and *Suarez* required more than generalized assertions of value; these courts found that internal and external exhortations that the business tools and value were insufficient. *See Forney*, 2017 WL 2653568, at *1, 5 (allegation that Medtronic touted value of business tool is insufficient to allege required value under AKS).[10]

More powerfully, unlike even in *Forney* and *Suarez*, tools like MA and RP are *available publicly*, through professional and community medical societies and listed on the Internet by other drug distributors and healthcare organizations.[11]

---

access to the Margin Analyzer on a stand-alone basis, McKesson refused." AC ¶ 70. However, McKesson's refusal to sell MA as a stand-alone product to non-customers, even if taken as true, is legally irrelevant as the MA is generated based on information concerning *sales from McKesson* (*see* AC ¶ 57). If a customer was not buying products from McKesson, there would be no sales data from McKesson to populate in the calculators. Certainly Relator never alleges that any of these customers purchased the analytic calculators after they ceased the McKesson relationship.

[10] *See, e.g.*, OIG Ad. Op. 00-10; OIG Adv. Op. 12-20 (finding a limited use interface did not constitute remuneration); OIG Adv. Op. 10-04, 2010 WL 1937992 (Apr. 30, 2010) (free preauthorization call center services provided by a Medical Center did not implicate the AKS); OIG Adv. Op. 10-20 (radiology group's provision of free insurance pre-authorization services to referring physicians did not constitute prohibited remuneration); OIG Adv. Op. 12-10, 2012 WL 4753657 (Aug. 23, 2012) (free insurance pre-authorization services to physicians and patients did not constitute prohibited remuneration).

[11] Under Rule 12(b)(6), a court "may consider all papers and exhibits appended to the complaint, as well as any matters of which judicial notice may be taken." *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1092 (2d Cir. 1995). "For purposes of a 12(b)(6) motion to dismiss, a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 179 n. 8 (S.D.N.Y. 2006). "Courts have considered newspaper articles, documents publicly filed with the SEC or FINRA,

First, for example, the American Society of Clinical Oncology ("ASCO"), the leading professional organization representing oncologists, the National Comprehensive Cancer Network ("NCCN")[12], and the Memorial Sloan Kettering Cancer Center have each developed and publicized tools to help providers and patients make informed and comparative decisions about the value of an oncology medicine or regimen. ASCO offers a "Value Framework" that allows oncologists to "assess the relative value of cancer treatment regimens that have been studied head-to-head in clinical trials."[13] ASCO's website states that the tool is needed because "[c]ancer costs are rising quickly, and cancer drugs are the fastest-growing component of these costs," concluding that "[p]hysicians have a responsibility to help address this problem."[14] Like the MA and RP tools, these ASCO tools allow physicians to compare reimbursement and profitability across competing medicines and treatment regimes. In addition to the web-based tool, ASCO also offers a free app with similar functionality.[15] The Memorial Sloan Kettering

---

documents filed with a Secretary of State, documents filed with governmental entities and available on their official websites, and information publicly announced on certain non-governmental websites, such as a party's official website." *Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015). Considering these materials does not transform this motion under Rule 12 into one for summary judgment under Rule 56. *See id.*

[12] The NCCN includes Evidence Blocks ("EB") Affordability Ratings in its Clinical Practice Guidelines, which "determines value based upon assigning scores to each drug in five areas-price, effectiveness, safety, quality, and consistency of clinical data." *See* Ex. B, Nat'l Comprehensive Cancer Network, Inc., *NCCN Evidence Blocks FAQs*, www.nccn.org/evidenceblocks/pdf/EvidenceBlocksFAQ.pdf.

[13] *See* Ex. C, Am. Soc'y of Clinical Oncology, *ASCO Value Framework Update: FAQs*, https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-May-Updated-Value-Framework-FAQ.pdf

[14] *Id.*

[15] *See* Ex. D, ASCO Guidelines Application, Google Play Store, https://play.google.com/store/apps/details?id=org.asco.guidelines&hl=en_(last visited Sept. 13, 2020).

Cancer Center has developed a "drug pricing lab" called "Drug Abacus," which is a web-based tool that allows users to estimate the "value" of a drug using an estimated price and reimbursement for the drug.[16] All these tools can be used to increase profitability, sometimes to increase or lower government reimbursement, but they are not kickbacks.

Second, other major drug distributors offer similar tools to their customers. Cardinal Health's website, for example, states that it offers customers "advanced technologies to help manage inventory, margins, reimbursement, emerging payment models and more."[17] The Cardinal website also describes web-based "Advance Practice Analytics for Oncology," which includes an online brochure with management tools that provide "margin analytics" and "[a]nalyze cost trends of targeted therapeutics across disease states."[18] The Cardinal website even includes a tool called Regimen Analyzer, which is described as a "web-based tool that allows you to quickly compare financial implications and clinical outcomes by regimen, drug and disease" and "[u]ncover new opportunities to optimize your drug spend, identify all eligible

---

[16] *See* Ex. E, *Drug Abacus,* Drug Pricing Lab, https://drugpricinglab.org/tools/drug-abacus/ (last visited Sept. 13, 2020). *See generally* Ex. F, Gary C. Yee, *Reimbursement for Expensive Cancer Therapies: The Role of Cost-effectiveness Analysis*, 1 Value-Based Cancer Care No. 1 (May 2010) www.valuebasedcancer.com/issues/2010/may-2010-vol-1-no-1/1457-reimbursement-for-expensive-cancer-therapies-the-role-of-cost-effectiveness-analysis (last visited Sept. 13, 2020) ("[A]lthough decision makers have been reluctant to consider cost effectiveness analyses in reimbursement decisions, there is increasing support for an expanded role of these types of analyses, including the creation of a new federally funded entity to produce these analyses.").

[17] Ex. G, *Practice Management*, Cardinal Health, www.cardinalhealth.com/en/services/specialty-physician-practice/resources/industry-insights/practice-management-resources.html (last visited Sept. 13, 2020).

[18] Ex. H, *Advance Practice Analytics from VitalSource GPO*, Cardinal Health (2019), https://www.cardinalhealth.com/content/dam/corp/web/documents/brochure/cardinal-health-advanced-practice-analytics-brochure.pdf. A video describes that these tools allow users to create "customizable reports" with which practices can "improve cash flow" and identify "savings opportunities in excess of $500k." *See* Cardinal Health Specialty Solutions, *Advanced Practice Analytics*, YouTube (Mar. 5, 2015) , www.youtube.com/watch?time_continue=62&v=J5B8KYG-mnM (last visited Sept. 13, 2020).

reimbursements and ultimately decrease your patients' financial burden."[19] Likewise, AmerisourceBergen has a tool named the "Protocol Analyzer," which offers "robust drug and protocol economic modeling" that "helps practices better manage their oncology drug spend and optimize their reimbursements."[20] Based on publicly available information, it appears that the tool allows practices to, among other things, "[a]nalyze economics of protocols," "[c]ompare reimbursement by payer for clinically equivalent drugs, and generate "Patient Financial Estimates," including co-pay estimates, to assist in discussions with patients.[21]

Finally, several healthcare entities offer MA and RP-type tools for free. NantHealth, offers a web-based tool that allows oncology practices to "[c]ompare treatment details including . . . costs" for "thousands of treatment regimens and clinical trials for all cancers and cancer subtypes."[22] The tool is available at no cost to oncology practices, requiring only that practices register on the company's website.[23] Via Oncology, which is owned by Elsevier, an information analytics business specializing in science and health, offers a system of three applications related to oncology drugs.[24] One application, Via Cost Analyzer, is publicly

---

[19] Ex. I, *Regimen Analyzer from VitalSource GPO*, Cardinal Health (2019), www.cardinalhealth.com/content/dam/corp/web/documents/brochure/cardinal-health-regimen-analyzer-brochure.pdf.

[20] Ex. J, *Protocol Analyzer,* ION Solutions, www.iononline.com/Solutions/Technology/Protocol-Analyzer (last visited Sept. 13, 2020).

[21] Ex. K, *Protocol Analyzer Overview,* ION Solutions, www.iononline.com/Solutions/Technology/Protocol-Analyzer/Protocol-Analyzer-Overview (last visited Sept. 13, 2020).

[22] Ex. L, *Eviti Advisor,* NantHealth Eviti, https://connect.eviti.com/evitiadvisor/ (last visited Sept. 13, 2020).

[23] Ex. M, *Eviti Advisor Fact Sheet*, Oncology Medical Home, http://www.medicalhomeoncology.org/UserFiles/eviti%20Advisor%20Fact%20Sheet.pdf.

[24] Ex. N, *ClinicalPath (formerly Via Oncology)*, Elsevier, https://www.elsevier.com/solutions/clinicalpath (last visited Sept. 13, 2020).

available and free and uses publicly available Medicare reimbursement information and provides information to oncology practices concerning treatment options.[25]

The AC, of course, acknowledges none of this publicly available information, preferring instead to characterize MA and RP as part of some secretive kickback scheme. Nor does the complaint acknowledge that the MA and RP tools themselves are referenced in publicly available materials, including on McKesson's own website.[26]

In short, if the physician office can get the business analytical tools for free off the Internet, or easily from other distributors, then they cannot provide substantial value. *See* OIG Adv. Op. 12-19 (AKS was not implicated where pharmacy provided free, unlimited access to a web-based software program to community health center homes); OIG Adv. Op. No. 07-16 (finding that home healthcare provider's free educational videos prior to surgery, did not implicate the AKS where "[s]imilar information content is available on the Internet and from other public sources without charge.").[27]

D. Like The Services Approved In Relevant OIG Guidance, The MA And RP Tools Provide No Independent Value.

Just as in *Forney* and *Suarez*, the AC does not adequately allege that MA and RP conferred independent value, much less *substantial* independent value, to the health care

[25] Ex. O, *Via Oncology Develops Regimen Costing Tool for Cancer Care Stakeholders*, PRWeb (Mar. 28, 2017), www.prweb.com/releases/viaoncology/viatriage/prweb14178448.htm#:~:text=The%20Via%20Cost%20Analyzer%20(VCA,insurance%20plan%20and%20patient%20characteristics (last visited Sept. 13, 2020).

[26] *See, e.g.*, Ex. A; Ex. P, *New Tools Arriving to Measure and Manage Chemotherapy Care*, 1 Value-Based Cancer Care No. 1 (May 2010), http://www.valuebasedcancer.com/issues/2010/may-2010-vol-1-no-1/1434-new-tools-arriving-to-measure-and-manage-chemotherapy-care (referencing Regimen Profiler along with AmerisourceBergen's Protocol Analyzer),

[27] The OIG also observed that any risk of substantial value was mitigated because a company's competitors offered a similar benefit at a similarly nominal cost. *See* OIG Adv. Op. 12-19.

providers who received them. The relevant OIG guidance and the cases make clear that business analytical tools do not have independent value — and thus do not violate the AKS — when they are "tied to the product purchased." *Forney*, 2017 WL 2653568, at *4. Thus, per OIG guidance, services like "billing assistance tailored to the purchased products" and "reimbursement consultation" are "specifically tied" to the purchased product and do not raise AKS concerns. 2003 OIG Guidance, 68 Fed. Reg. at 23,735. The AC contains the same type of conclusory allegations concerning the value of MA and RP as were found deficient in cases applying this OIG guidance. Like the *Forney* and *Suarez* cases, the AC does not allege how RP and MA "cross[] the line separating permissible product support from illegal remuneration with independent value." *Forney*, 2017 WL 2653568, at *4.

To the contrary, the AC repeatedly acknowledges that the MA and RP tools were related to the medicines that McKesson was distributing. According to the AC, the tools were only available to the customers who "commit to use McKesson either as its primary wholesale supplier" or for customers who committed to use McKesson for "substantially all of its branded and generic drug needs," AC ¶ 69, and could not be maintained if the customers went to another distributor, AC ¶ 70. Indeed, if the customer did not purchase any medicines from McKesson, then the MA and RP tools would lack the key pricing comparisons about which relator complains. Much like limited use computers, electronic interfaces, and reimbursement support services related to a company's medicines, the MA and RP tools convey information that is integrally related to the McKesson relationship. The MA is virtually meaningless to practices that do not purchase from McKesson.

Nor can Relator allege that the MA and RP tools allowed the physician offices to avoid or reduce expenses otherwise required in the ordinary course of business. The AC, in fact, does not

even allege to the contrary. Just like the relator in *Forney*, Hart fails to allege "which of the services that [McKesson] provided in exchange for purchasing [McKesson] products would have had to have been otherwise performed by the physician or the physician's staff." *See Forney*, 2017 WL 2653568, at *4;. OIG Adv. Op. No. 08-20, 2008 WL 6067530, at *4 (Nov. 19, 2008) (concluding that patient training services provided by a medical equipment company did not "substitute for services currently provided by the hospitals" and therefore did not violate the AKS); *cf.* OIG Adv. Op. 12-19 (noting that a service can have independent value when it helps the recipient avoid incurring administrative costs and obligations imposed by regulations).[28]

II. The AC Must Be Dismissed Because It Does Not Sufficiently Allege A Knowing And Willful Violation Of The AKS.

Not only does Hart fail to allege that the MA and RP tools were prohibited remuneration under the AKS, he also fails to allege that Defendant acted with knowledge that its conduct was unlawful, as required to establish a violation of the AKS.

To prove a violation of the FCA using the AKS, the relator must prove the defendant's knowing and willful intent, which requires a showing that the company knew its conduct was unlawful. 42 U.S.C. § 1320a-7b; *Gonzalez v. Fresenius Med. Care N. Am.*, 689 F.3d 470, 476 (5th Cir. 2012) (declining to find FCA violation where relator did not provide legally sufficient evidence that [defendants] knowingly and willfully entered into an illegal kickback scheme); *U.S. ex rel. Osheroff v. Tenet Healthcare Corp.*, No. 09-22253-CIV, 2012 WL 2871264, at *8 (S.D. Fla. July 12, 2012) (quoting *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998));

[28] *U.S. ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 265 (D. Mass. 2016), is not to the contrary. While the court found Medtronic's billing and reimbursement support permissible, as they were related to the Medtronic products, the court denied Medtronic's motion to dismiss because the relator had also alleged that Medtronic provided staff to actually run clinics at doctors' offices. *Id.* at 269–70. There is, of course, no similar allegation here.

see also Gonzalez, 689 F.3d at 476. A company cannot be found to have violated the AKS "merely because he sought to cultivate a business relationship or create a reservoir of goodwill that might ultimately affect one or more unspecified purchase or order decisions. Substantive Jury Instructions at 5, *United States v. Reichel*, No. 15-cr-10324-DPW, (D. Mass. Jun. 17, 2016), ECF No. 244; *see also United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000) (holding that the AKS is not violated where a defendant merely "hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes").

Instead, to satisfy the AKS's "heightened intent requirement," the relator must show "'that the defendant realized what he was doing and was aware of the nature of his conduct, and did not act through ignorance, mistake, or accident.'" *Klaczak ex rel. U.S. v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 674 (N.D. Ill. 2006); *see United States v. Bay State Ambulance & Hop. Rental Serv., Inc.*, 874 F.2d 20, 33 (1st Cir. 1989) (describing knowing and willful intent: "Knowingly simply means to do something voluntarily, to do it deliberately, not to do something by mistake or by accident or even negligently. Willfully means to do something purposely, with the intent to violate the law, to do something purposely that the law forbids.").

The AC does not even allege that "any [McKesson] employee knew that providing free services violated the AKS." *See Forney*, 2017 WL 2653568, at *5. Hart makes the conclusory allegation that "McKesson intentionally decided to employ these illegal kickbacks," but merely saying a company intentionally offered a program that now is alleged to be a kickback is insufficient. *See id.* at *5 (finding AKS scienter requirement not satisfied where relator alleged that "Medtronic induced physicians and others with purchasing power to select Medtronic devices" (internal quotation marks omitted)). Instead, the AC must allege that McKesson knew that its MA and RP tools were wrongful and illegal, not just that a defendant intentionally

offered a business analytical tool that a customer might like. *Cf. United States v. Shaw*, 106 F. Supp. 2d 103, 120 (D. Mass. 2000) (finding mere business motive, without more, "is not sufficient to support a finding of the state of mind necessary to convict under the [AKS]"). There is no allegation that a single employee, much less the company, knew it was doing anything wrong, much less knew that the MA or RP tools violated the AKS, even though Hart claims to have worked closely with McKesson personnel for years. The AC does not and cannot allege that a single employee of McKesson knew that providing MA and RP would constitute unlawful kickbacks. Certainly the AC never explains how the company knew its conduct was wrong given that it explained these tools on its website, *supra* p. 18 n.29, just as many other organizations discussed their own analytic calculators, *supra* p. 15–17.

This is especially true where the OIG guidance supports McKesson's belief that its services were in fact lawful. *See U.S. ex rel. Banigan v. Organon USA Inc.*, No. 07-12153-RWZ, 2016 WL 10704126, at *4 (D. Mass. Aug. 23, 2016) (stating that "a 'not objectively unreasonable' navigation of a regulatory thicket surrounding the AKS would negate the necessary scienter"). Under these circumstances, Hart has failed to plead sufficient facts identifying anyone from McKesson who allegedly "knew" that the Company's business analytical tools were unlawful, and the AC must be dismissed for this separate reason alone.

III. The AC Must Be Dismissed Because It Does Not Plead With Particularity That False Claims Were Submitted To The Government As A Result Of McKesson Providing MA Or RP.

Even beyond the failure to allege prohibited remuneration and the required specific intent, the AC should be dismissed under Rule 9(b) because it fails to identify a single false claim, nor does it allege facts that allow the court to "'adduce specific facts supporting a strong inference of fraud.'" *Chorches*, 865 F.3d at 82 (internal citation omitted). Where an FCA claim is premised on violations of the AKS, plaintiff must "plead with particularity the 'who, what,

when, where and how' of the fraudulent . . . scheme." *U.S. ex rel. Mooney v. Americare, Inc.*, No. 06 Civ. 1806, 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013). The AC fails to meet these requirements because it does not provide the minimum information necessary under Rule 9(b).

Even though this is a case brought under the False Claims Act, the AC fails to identify a single false claim or plead specific facts supporting a strong inference of fraud. There are a few specific customers who are alleged to have received the MA and RP tools, and a generalized allegation that physician practices "submitted hundreds of millions of dollars' worth of claims for reimbursement," AC ¶ 8, but that is it. All that is alleged is that "[o]n information and belief," various unnamed customers submitted unidentified claims in various states. AC ¶ 122. There is no allegation of how or whether these customers used MA and RP, which medicines were prescribed, much less whether they were prescribed because of MA and RP. And there is nothing about whether any of these customers submitted a single claim connected to the use of the MA and RP tools. Simply postulating that some undetermined number of physicians, on some undetermined dates, must have prescribed medicines because McKesson provided the MA and RP tools, is not enough. In other words, "ask[ing] [the court] to infer that a portion of these funds must have been used to pay unlawful claims . . . do[es] not suffice under Rule 9(b)." *Lawton ex rel. U.S. v. Takeda Pharm. Co.*, 842 F.3d 125, 131–32 (1st Cir. 2016); *see also United States ex rel. Chapman v. Office of Children's & Family Servs.*, No. 04-1505, 2010 WL 610730, at *4 (N.D.N.Y. Feb. 16, 2010) (dismissing complaint encompassing 82 pages because it failed to meet the Rule 9(b) particularity requirement and noting the relator "summarily conclude[d] that the defendants submitted false claims to the government . . . .").

That is plainly insufficient under Second Circuit law. In *U.S. ex rel. Gelbman v. City of New York*, 790 F. App'x 244 (2d Cir. 2019), for example, the relator alleged that employees of

the New York State Department of Health ("DOH") "conspired to manipulate and rig" an automated system used to determine whether Medicaid claims were reimbursable. *Id.* at 246. The relator, a DOH employee, alleged that he learned about the misconduct at meetings with City employees, where he personally questioned the challenged practices. *Id.* at 246–47. He also alleged that he possessed "files and records" showing that the federal government had paid five categories of improper claims, and he provided "detailed payment information for more than 80 individual exemplar claims." *Id.* at 247 (internal quotations omitted). Even though the relator in that case, unlike here, identified specific false claims and specific records, the Second Circuit nonetheless affirmed the dismissal of the relator's claims under Rule 9(b) because the relator failed to allege "how [the system] was rigged" or "who carried out the rigging." *Id.* at 248. Because of these deficiencies, the court was "left to speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government." *Id.* at 249.

Hart's allegations are also far less detailed than those found sufficient by the Second Circuit in *Chorches*, 865 F.3d. In that case, the relator satisfied Rule 9(b) because he identified "supervisory personnel" who instructed individuals to falsify specific information, described specific instances in which he "was told to alter a [document] with false or misleading information," and detailed threats by supervisors to make such alterations. *See id.* at 83–84. The relator also described specific instances, with dates, in which false records were submitted to Medicare for payment. *See, e.g. id.* at 84. Hart makes no such allegations here. *See Ping*, 966 F. Supp. 2d at 302 (dismissing claims because no particular false claim has been identified).

The Fifth Circuit also dismissed even more specific allegations in *U.S. ex rel. Nunnally v. West Calcasieu Cameron Hospital*, 519 F. App'x 890 (5th Cir. 2013). There, the court held that the relator failed to satisfy Rule 9(b) because his allegations of "verbal agreements" that

allegedly induced physicians to provide improper referrals were not accompanied by "information on the contents of those agreements, the identity of any physicians, actual inducements, or improper referrals." *Id.* at 894 (internal quotations omitted). Although the relator described an "example of an agreement to charge physicians $3.60 for a blood test, while later charging Medicare $10.60," this allegation did not "specify who in particular was involved in this agreement, or how it constituted an illegal kickback." *Id.*

Hart's complaint provides even less detail than the complaints rejected by the Second and Fifth Circuits in *Gelbman* and *Nunnally*. Hart does not provide a single "example," as in *Nunnally*, of any specific false claim, or prescription caused by using the MA and RP tools. The whole case is based on a series of assumptions — that physicians would make prescription decisions based on the MA and RP tools, as opposed to clinical and efficacy reasons; that the practices become more profitable as a result; that government reimbursement must have risen (even though the MA contained examples of lower cost generics); and that false claims must have been submitted based on those prescriptions. Asking the Court to complete these various connections between MA and RP and any eventual claims is not permissible, particularly when the relator claims to be an insider and asserts that he had access to detailed information concerning MA and RP. *See* AC ¶ 14. The AC should also be dismissed for this reason alone.

CONCLUSION

For the foregoing reasons, the Court should dismiss the AC with prejudice.

Dated: September 30, 2020

Respectfully submitted,

/s/ Elisa S. Solomon

Elisa S. Solomon
COVINGTON & BURLING LLP
The New York Times Building
620 Eighth Avenue

New York, New York 10018
esolomon@cov.com

Ethan M. Posner*
Shanya Dingle
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001
Tel: 202.662.6000
eposner@cov.com
sdingle@cov.com
**Pro hac vice application to be filed*

Attorneys for Defendants